General

Guideline Title

Pressure ulcers: prevention and management of pressure ulcers.

Bibliographic Source(s)

National Clinical Guideline Centre. Pressure ulcers: prevention and management of pressure ulcers. London (UK): National Institute for Health and Care Excellence; 2014 Apr. 37 p. (Clinical guideline; no. 179).

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Nursing, National Institute for Health and Clinical Excellence (NICE). The management of pressure ulcers in primary and secondary care. A clinical practice guideline. London (UK): Royal College of Nursing; 2005 Sep 22. 245 p. [485 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation) and is defined at the end of the "Major Recommendations" field.

Terms Used in This Guideline

Adults, Neonates, Infants, Children and Young People

This guideline covers people of all ages at risk of, or who have, a pressure ulcer. These terms are defined as follows:

- Adults: 18 years or older
- Neonates: under 4 weeks
- Infants: between 4 weeks and 1 year
- Children: 1 year to under 13 years
- Young people: 13 to 17 years

Risk Assessment

This guideline uses the terms 'at risk' and 'at high risk' to identify people who may develop a pressure ulcer. For the purposes of this guideline:

- Adults considered to be at risk of developing a pressure ulcer are those who, after assessment using clinical judgement and/or a validated risk assessment tool, are considered to be at risk of developing a pressure ulcer.
- Adults considered to be at high risk of developing a pressure ulcer will usually have multiple risk factors (for example, significantly limited mobility, nutritional deficiency, inability to reposition themselves, significant cognitive impairment*) identified during risk assessment with or without a validated risk assessment tool. Adults with a history of pressure ulcers or a current pressure ulcer are also considered to be at high risk.
- Neonates, infants, children and young people considered to be at risk are those who, after assessment using clinical judgement and/or a validated risk assessment tool, are considered to be at risk of developing a pressure ulcer.
- Neonates, infants, children and young people considered to be at high risk of developing a pressure ulcer will usually have multiple risk factors (for example, significantly limited mobility, nutritional deficiency, inability to reposition themselves, significant cognitive impairment*) identified during risk assessment with or without a validated risk assessment tool. Those with a history of pressure ulcers or a current pressure ulcer are also considered to be at high risk.

*Please note that the examples given are not exhaustive.

Prevention: Adults

Risk Assessment

Be aware that all patients are potentially at risk of developing a pressure ulcer.

Carry out and document an assessment of pressure ulcer risk for adults:

- Being admitted to secondary care or care homes in which National Health Service (NHS) care is provided
- Receiving NHS care in other settings (such as primary and community care and emergency departments) if they have a risk factor, for example:
    - Significantly limited mobility (for example, people with a spinal cord injury)
    - Significant loss of sensation
    - A previous or current pressure ulcer
    - Nutritional deficiency
    - The inability to reposition themselves
    - Significant cognitive impairment

Consider using a validated scale to support clinical judgement (for example, the Braden scale, the Waterlow score or the Norton risk-assessment scale) when assessing pressure ulcer risk.

Reassess pressure ulcer risk if there is a change in clinical status (for example, after surgery, on worsening of an underlying condition or with a change in mobility).

Skin Assessment

Offer adults who have been assessed as being at high risk of developing a pressure ulcer a skin assessment by a trained healthcare professional (see recommendations under "Healthcare Profession Training and Education" below). The assessment should take into account any pain or discomfort reported by the patient and the skin should be checked for:

- Skin integrity in areas of pressure
- Colour changes or discoloration**
- Variations in heat, firmness and moisture (for example, because of incontinence, oedema, dry or inflamed skin).

Use finger palpation or diascopy to determine whether erythema or discolouration (identified by skin assessment) is blanchable.

Start appropriate preventative action (see recommendations in previous section) in adults who have non-blanching erythema and consider repeating the skin assessment at least every 2 hours until resolved.

**Healthcare professionals should be aware that non-blanchable erythema may present as colour changes or discolouration, particularly in darker skin tones or types.

Repositioning

Encourage adults who have been assessed as being at risk of developing a pressure ulcer to change their position frequently and at least every 6 hours. If they are unable to reposition themselves, offer help to do so, using appropriate equipment if needed. Document the frequency of repositioning required.

Encourage adults who have been assessed as being at high risk of developing a pressure ulcer to change their position frequently and at least every 4 hours.

If they are unable to reposition themselves, offer help to do so, using appropriate equipment if needed. Document the frequency of repositioning required.

Skin Massage

Do not offer skin massage or rubbing to adults to prevent a pressure ulcer.

Nutritional Supplements and Hydration

Do not offer nutritional supplements specifically to prevent a pressure ulcer in adults whose nutritional intake is adequate.

Do not offer subcutaneous or intravenous fluids specifically to prevent a pressure ulcer in adults whose hydration status is adequate.

Pressure Redistributing Devices

Use a high-specification foam mattress for adults who are:

- Admitted to secondary care
- Assessed as being at high risk of developing a pressure ulcer in primary and community care settings

Consider a high-specification foam theatre mattress or an equivalent pressure redistributing surface for all adults who are undergoing surgery.

Discuss with adults at high risk of developing a heel pressure ulcer and, where appropriate, their family or carers, a strategy to offload heel pressure, as part of their individualised care plan.

Consider the seating needs of people at risk of developing a pressure ulcer who are sitting for prolonged periods.

Consider a high-specification foam or equivalent pressure redistributing cushion for adults who use a wheelchair or who sit for prolonged periods.

Barrier Creams

Consider using a barrier preparation to prevent skin damage in adults who are at high risk of developing a moisture lesion or incontinence-associated dermatitis, as identified by skin assessment (such as those with incontinence, oedema, dry or inflamed skin).

Prevention: Neonates, Infants, Children and Young People

Risk Assessment

Carry out and document an assessment of pressure ulcer risk for neonates, infants, children and young people:

- Being admitted to secondary or tertiary care
- Receiving NHS care in other settings (such as primary and community care and emergency departments)if they have a risk factor, for example:
    - Significantly limited mobility
    - Significant loss of sensation
    - A previous or current pressure ulcer
    - Nutritional deficiency
    - The inability to reposition themselves
    - Significant cognitive impairment

Use a scale validated for this population (for example, the Braden Q scale for children), to support clinical judgement.

Skin Assessment

Offer neonates, infants, children and young people who are assessed as being at high risk of developing a pressure ulcer a skin assessment by a trained healthcare professional. Take into account:

- Skin changes in the occipital area
- Skin temperature
- The presence of blanching erythema or discoloured areas of skin

Be aware of specific sites (for example, the occipital area) where neonates, infants, children and young people are at risk of developing a pressure ulcer.

Repositioning

Ensure that neonates and infants who are at risk of developing a pressure ulcer are repositioned at least every 4 hours.

Encourage children and young people who are at risk of developing a pressure ulcer to change their position at least every 4 hours. If they are unable to reposition themselves, offer help to do so, using appropriate equipment if needed.

Consider more frequent repositioning than every 4 hours for neonates and infants who have been assessed as being at high risk of developing a pressure ulcer. Document the frequency of repositioning required.

Encourage children and young people who have been assessed as being at high risk of developing a pressure ulcer to change their position more frequently than every 4 hours. If they are unable to reposition themselves, offer help to do so, using equipment if needed. Document the frequency of repositioning required.

Ensure that repositioning equipment is available to aid the repositioning of children and young people, if needed.

Ensure that healthcare professionals are trained in the use of repositioning equipment.

Ensure that patients, parents and carers understand the reasons for repositioning. If children and young people decline repositioning, document and discuss their reasons for declining.

Consider involving a play expert to encourage children who have difficulty with or who have declined repositioning.

Relieve pressure on the scalp and head when repositioning neonates, infants, children and young people at risk of developing a pressure ulcer.

Skin Massage

Do not offer skin massage or rubbing to neonates, infants, children and young people to prevent a pressure ulcer.

Nutritional Supplements and Hydration

Do not offer nutritional supplements specifically to prevent a pressure ulcer in neonates, infants, children and young people with adequate nutritional status for their developmental stage and clinical condition.

Do not offer subcutaneous or intravenous fluids specifically to prevent a pressure ulcer in neonates, infants, children and young people with adequate hydration status for their development stage and clinical condition.

Pressure Redistributing Devices

Use a high-specification foam cot mattress or overlay for all neonates and infants who have been assessed as being at high risk of developing a pressure ulcer as part of their individualised care plan.

Use a high-specification foam mattress or overlay for all children and young people who have been assessed as being at high risk of developing a pressure ulcer as part of their individualised care plan.

Discuss with children and young people at high risk of developing a heel pressure ulcer and their parents and carers, where appropriate, a strategy to offload heel pressure as part of their individualised care plan.

Offer infants, children and young people who are long-term wheelchair users regular wheelchair assessments and provide pressure relief or redistribution.

Offer neonates, infants, children and young people at risk of developing an occipital pressure ulcer an appropriate pressure redistributing surface (for example, a suitable pillow or pressure redistributing pad).

Barrier Creams

Use barrier preparations to help prevent skin damage, such as moisture lesions, for neonates, infants, children and young people who are incontinent.

Prevention: All Ages

Care Planning

Develop and document an individualised care plan for neonates, infants, children, young people and adults who have been assessed as being at high risk of developing a pressure ulcer, taking into account:

- The outcome of risk and skin assessment
- The need for additional pressure relief at specific at-risk sites
- Their mobility and ability to reposition themselves
- Other comorbidities
- Patient preference

Patient and Carer Information

Offer timely, tailored information to people who have been assessed as being at high risk of developing a pressure ulcer, and their family or carers. The information should be delivered by a trained or experienced healthcare professional and include:

- The causes of a pressure ulcer
- The early signs of a pressure ulcer
- Ways to prevent a pressure ulcer
- The implications of having a pressure ulcer (for example, for general health, treatment options and the risk of developing pressure ulcers in the future)

Demonstrate techniques and equipment used to prevent a pressure ulcer.

Take into account individual needs when supplying information to people with:

- Degenerative conditions
- Impaired mobility
- Neurological impairment
- Cognitive impairment
- Impaired tissue perfusion (for example, caused by peripheral arterial disease)

Healthcare Professional Training and Education

Provide training to healthcare professionals on preventing a pressure ulcer, including:

- Who is most likely to be at risk of developing a pressure ulcer
- How to identify pressure damage
- What steps to take to prevent new or further pressure damage
- Who to contact for further information and for further action

Provide further training to healthcare professionals who have contact with anyone who has been assessed as being at high risk of developing a pressure ulcer. Training should include:

- How to carry out a risk and skin assessment
- How to reposition
- Information on pressure redistributing devices
- Discussion of pressure ulcer prevention with patients and their carers
- Details of sources of advice and support

Management: Adults

Ulcer Measurement

Document the surface area of all pressure ulcers in adults. If possible, use a validated measurement technique (for example, transparency tracing or a photograph).

Document an estimate of the depth of all pressure ulcers and the presence of undermining, but do not routinely measure the volume of a pressure ulcer.

Categorisation

Categorise each pressure ulcer in adults using a validated classification tool (such as the International National Pressure Ulcer Advisory Panel-European Pressure Ulcer Advisory Panel [NPUAP-EPUAP] [2009] Pressure Ulcer Classification System). Use this to guide ongoing preventative strategies and management. Repeat and document each time the ulcer is assessed.

Nutritional Supplements and Hydration

Offer adults with a pressure ulcer a nutritional assessment by a dietitian or other healthcare professional with the necessary skills and competencies.

Offer nutritional supplements to adults with a pressure ulcer who have a nutritional deficiency.

Provide information and advice to adults with a pressure ulcer and, where appropriate, their family or carers, on how to follow a balanced diet to maintain an adequate nutritional status, taking into account energy, protein and micronutrient requirements.

Do not offer nutritional supplements to treat a pressure ulcer in adults whose nutritional intake is adequate.

Do not offer subcutaneous or intravenous fluids to treat a pressure ulcer in adults whose hydration status is adequate.

Pressure Redistributing Devices

Use high-specification foam mattresses for adults with a pressure ulcer. If this is not sufficient to redistribute pressure, consider the use of a dynamic support surface.

Do not use standard-specification foam mattresses for adults with a pressure ulcer.

Consider the seating needs of adults who have a pressure ulcer who are sitting for prolonged periods.

Consider a high-specification foam or equivalent pressure redistributing cushion for adults who use a wheelchair or sit for prolonged periods and who have a pressure ulcer.

Negative Pressure Wound Therapy

Do not routinely offer adults negative pressure wound therapy to treat a pressure ulcer, unless it is necessary to reduce the number of dressing changes (for example, in a wound with a large amount of exudate).

Hyperbaric Oxygen Therapy and Electrotherapy

Do not offer the following to adults to treat a pressure ulcer:

- Electrotherapy
- Hyperbaric oxygen therapy

Debridement

Assess the need to debride a pressure ulcer in adults, taking into consideration:

- The amount of necrotic tissue
- The grade, size and extent of the pressure ulcer
- Patient tolerance
- Any comorbidities

Offer debridement to adults if identified as needed in the assessment:

- Use autolytic debridement, using an appropriate dressing to support it.
- Consider using sharp debridement if autolytic debridement is likely to take longer and prolong healing times.

Do not routinely offer adults with a pressure ulcer:

- Larval (maggot) therapy
- Enzymatic debridement

Consider larval therapy if debridement is needed but sharp debridement is contraindicated or if there is associated vascular insufficiency.

Systemic Antibiotics and Antiseptics

After a skin assessment, offer systemic antibiotics to adults with a pressure ulcer if there are any of the following:

- Clinical evidence of systemic sepsis
- Spreading cellulitis
- Underlying osteomyelitis

Discuss with a local hospital microbiology department which antibiotic to offer adults with infection to ensure that the chosen systemic antibiotic is effective against local strains of infection.

Do not offer systemic antibiotics specifically to heal a pressure ulcer in adults.

Do not offer systemic antibiotics to adults based only on positive wound cultures without clinical evidence of infection.

Topical Antimicrobials and Antiseptics

Do not routinely use topical antiseptics or antimicrobials to treat a pressure ulcer in adults.

Dressings

Discuss with adults with a pressure ulcer and, if appropriate, their family or carers, what type of dressing should be used, taking into account:

- Pain and tolerance
- Position of the ulcer
- Amount of exudate
- Frequency of dressing change

Consider using a dressing for adults that promotes a warm, moist wound healing environment to treat grade 2, 3 and 4 pressure ulcers.

Do not offer gauze dressings to treat a pressure ulcer in adults.

Heel Pressure Ulcers

Discuss with adults with a heel pressure ulcer and, if appropriate, their family or carers, a strategy to offload heel pressure as part of their individualised care plan.

Management: Neonates, Infants, Children and Young People

Ulcer Measurement

Document the surface area of all pressure ulcers in neonates, infants, children and young people, preferably using a validated measurement technique (for example, transparency tracing or a photograph).

Document an estimate of the depth of a pressure ulcer and the presence of undermining, but do not routinely measure the volume of a pressure ulcer in neonates, infants, children and young people.

Categorisation

Categorise each pressure ulcer in neonates, infants, children and young people at onset using a validated classification tool (such as the International NPUAP-EPUAP [2009]) Pressure Ulcer Classification System) to guide ongoing preventative and management options. Repeat and document each time the ulcer is assessed.

Nutritional Supplements and Hydration

Offer an age-related nutritional assessment to neonates, infants, children and young people with a pressure ulcer. This should be performed by a

paediatric dietitian or other healthcare professional with the necessary skills and competencies.

Discuss with a paediatric dietitian (or other healthcare professional with the necessary skills and competencies) whether to offer nutritional supplements specifically to treat a pressure ulcer in neonates, infants, children and young people whose nutritional intake is adequate.

Offer advice on a diet that provides adequate nutrition for growth and healing in neonates, infants, children and young people with a pressure ulcer.

Discuss with a paediatric dietitian whether to offer nutritional supplements to correct nutritional deficiency in neonates, infants, children and young people with a pressure ulcer.

Assess fluid balance in neonates, infants, children and young people with a pressure ulcer.

Ensure there is adequate hydration for age, growth and healing in neonates, infants, children and young people. If there is any doubt, seek further medical advice.

Pressure Redistributing Devices

Consider using specialist support surfaces (including dynamic support surfaces where appropriate) for neonates, infants, children and young people with a pressure ulcer, taking into account their current pressure ulcer risk and mobility.

Use a high-specification cot or bed mattress or overlay for all neonates, infants, children and young people with a pressure ulcer.

If pressure on the affected area cannot be adequately relieved by other means (such as repositioning), consider a dynamic support surface, appropriate to the size and weight of the child or young person with a pressure ulcer, if this can be tolerated.

Tailor the support surface to the location and cause of the pressure ulcer for neonates, infants, children and young people.

Negative Pressure Wound Therapy

Do not routinely use negative pressure wound therapy to treat a pressure ulcer in neonates, infants, children and young people.

Hyperbaric Oxygen Therapy and Electrotherapy

Do not use the following to treat a pressure ulcer in neonates, infants, children and young people:

- Electrotherapy
- Hyperbaric oxygen therapy

Debridement

Consider autolytic debridement with appropriate dressings for dead tissue in neonates, infants, children and young people. Consider sharp and surgical debridement by trained staff if autolytic debridement is unsuccessful.

Systemic Antibiotics and Antiseptics

Consider systemic antibiotics for neonates, infants, children and young people with a pressure ulcer with clinical evidence of local or systemic infection.

Discuss with a local hospital microbiology department which antibiotic to offer neonates, infants, children and young people with infection to ensure that the chosen systemic antibiotic is effective against local strains of bacteria.

Topical Antimicrobials and Antiseptics

Do not routinely use topical antiseptics or antimicrobials to treat a pressure ulcer in neonates, infants, children and young people.

Dressings

Consider using a dressing that promotes a warm, moist healing environment to treat grade 2, 3 and 4 pressure ulcers in neonates, infants, children and young people.

Consider using topical antimicrobial dressings to treat a pressure ulcer where clinically indicated in neonates, infants, children and young people, for example, where there is spreading cellulitis.

Do not use iodine dressings to treat a pressure ulcer in neonates.

Do not offer gauze dressings to treat a pressure ulcer in neonates, infants, children and young people.

Heel Pressure Ulcers

Discuss with the parents or carers of neonates and infants and with children and young people (and their parents or carers if appropriate), a strategy to offload heel pressure as part of their individualised care plan to manage their heel pressure ulcer, taking into account differences in size, mobility, pain and tolerance.

Definitions:

Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally 'must' (or 'must not') is used if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer…') are used when the GDG is confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Clinical Algorithm(s)

The following algorithms are provided on the National Institute for Health and Care Excellence (NICE) Web site :

- Algorithm for risk assessment, prevention and management in children
- Algorithm for risk assessment, prevention and management in adults

A NICE care pathway titled "Pressure Ulcers Overview" is available on the NICE Web site .

Scope

Disease/Condition(s)

Pressure ulcers

Other Disease/Condition(s) Addressed

- Nutritional deficiency
- Incontinence

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Treatment

Clinical Specialty

Critical Care

Dermatology

Family Practice

Geriatrics

Internal Medicine

Nursing

Nutrition

Pediatrics

Physical Medicine and Rehabilitation

Plastic Surgery

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Hospitals

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

- To update and replace two previous National Institute for Health and Care Excellence (NICE) guidelines: 'Pressure ulcers', NICE clinical

guideline 29 (2005) and 'Pressure ulcer prevention', NICE clinical guideline 7 (2003)
- To rationalise the approaches used for the prevention and management of pressure ulcers

Target Population

People of all ages, including all adults and children, in home, primary care, and secondary care settings

Interventions and Practices Considered

Prevention/Risk Assessment

1. Risk assessment for pressure ulcer using a validated scale to support clinical judgement (e.g., Braden scale [Braden Q scale for children], Waterlow score, Norton risk assessment scale)
2. Skin assessment (skin integrity; colour changes; variation in heat, firmness, moisture; skin changes in occipital area in children)
3. Repositioning
4. Skin massage (not recommended)
5. Nutritional supplements and hydration (not recommended for prevention)
6. Pressure redistributing devices
7. Barrier creams
8. Care planning
9. Providing patient and carer information about pressure ulcers and their prevention
10. Providing healthcare professional training and education

Management/Treatment

1. Ulcer measurement
2. Categorising each pressure ulcer using a validated classification tool
3. Nutritional assessment and nutritional supplements and hydration
4. Pressure redistributing devices
5. Negative pressure wound therapy (not recommended routinely)
6. Hyperbaric oxygen therapy and electrotherapy (not recommended)
7. Debridement (autolytic, sharp)
8. Larval or enzymatic debridement (not recommended routinely)
9. Systemic antibiotics when appropriate
10. Topical antimicrobials and antiseptics (not recommended routinely)
11. Dressings
12. Offloading heel pressure

Major Outcomes Considered

- Sensitivity and specificity of assessment tools
- Rate of development of pressure ulcers
- Time to develop new pressure ulcer
- Time in hospital, other health care institution, or National Health Service (NHS) care
- Health-related quality of life as measured by assessment tools
- Skin damage
- Patients acceptability of supplements or treatments – e.g., measured by compliance and tolerance
- Side effects
- Accuracy and reliability of categorization system
- Time and ease of use of classification system
- Time to complete healing
- Rate of complete healing
- Rate in change of size of ulcer

- Proportion of patients completely healed within trial period
- Pain
- Mortality

See Appendix C in the full version of the original guideline document for additional details and discussion.

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Developing the Review Questions and Outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention reviews, using population, presence or absence of factors under investigation (for example, prognostic factors) and outcomes for prognostic reviews.

This use of a framework guided the literature searching process, critical appraisal and synthesis of evidence, and facilitated the development of recommendations by the Guideline Development Group (GDG). The review questions were drafted by the NCGC technical team and refined and validated by the GDG. The GDG chose approximately 7 outcomes identifying which outcomes were critical to their decision making and which were important. This distinction helped the GDG to make judgements about the importance of the different outcomes and their impact on decision making. For example, proportion of people with pressure ulcers healed will usually be considered a critical outcome and would be given greater weight when considering the clinical effectiveness of an intervention than an important outcome with less serious consequences. The GDG decide on the relative importance in the review protocol before seeing the review. The questions were based on the key clinical issues identified in the scope (see Appendix A in the full version of the original guideline document).

A total of 25 review questions were identified.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

Searching for Evidence

Clinical Literature Search

The aim of the literature search was to identify all available, relevant published evidence in relation to the key clinical questions generated by the GDG. Systematic literature searches were undertaken to identify evidence within the published literature in order to answer the review questions as per The Guidelines Manual (2009) (see the "Availability of Companion Documents" field). Clinical databases were searched using relevant medical subject headings, free-text terms and study type filters where appropriate. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in the English language. All searches were conducted on core databases, MEDLINE, EMBASE, CINAHL and The Cochrane Library. All searches were updated on 28th August 2013. No papers published after this date were considered.

Search strategies were checked by looking at reference lists of relevant key papers, checking search strategies in other systematic reviews and asking the GDG for known studies in a specific area. The questions, the study types applied, the databases searched and the years covered can be found in Appendix F in the full version of the original guideline document.

During the scoping stage, a search was conducted for guidelines and reports on the websites listed below and on organisations relevant to the

topic. Searching for grey literature or unpublished literature was not undertaken. All references sent by stakeholders were considered.

- Guidelines International Network database (www.g-i-n.net)
- National Guideline Clearinghouse (www.guideline.gov/)
- National Institute for Health and Care Excellence (NICE) (www.nice.org.uk)
- National Institutes of Health Consensus Development Program (consensus.nih.gov/)
- Health Information Resources, NHS Evidence (www.library.nhs.uk/)

The titles and abstracts of records retrieved by the searches were scanned for relevance to the GDG's review questions. Any potentially relevant publications were obtained in full text. These were assessed against the inclusion criteria and the reference lists were scanned for any articles not previously identified. Further references were also suggested by the GDG.

Health Economic Literature Search

Systematic literature searches were also undertaken to identify health economic evidence within the published literature relevant to the review questions. The evidence was identified by conducting a broad search relating to the guideline population in the NHS economic evaluation database (NHS EED), the Health Economic Evaluations Database (HEED) and health technology assessment (HTA) databases with no date restrictions. Additionally, the search was run on MEDLINE and EMBASE, with a specific economic filter, to ensure recent publications that had not yet been indexed by these databases were identified. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in the English language.

The search strategies for health economics are included in Appendix F in the full version of the original guideline document. All searches were updated on 28th August 2013. No papers published after this date were considered.

Evidence of Effectiveness

The evidence was reviewed following the steps shown schematically in Figure 1 in the full version of the original guideline document:

- Potentially relevant studies were identified for each review question from the relevant search results by reviewing titles and abstracts. Full papers were then obtained.
- Full papers were reviewed against pre-specified inclusion/exclusion criteria to identify studies that addressed the review question in the appropriate population (review protocols are included in Appendix C in the full version of the original guideline document).

The inclusion/exclusion of studies was based on the review protocols (Appendix C in the full version of the original guideline document). The GDG were consulted about any uncertainty regarding inclusion/exclusion.

The guideline population was defined to be adults, children and young people with pressure ulcers. There was an overall lack of evidence for children and since recommendations for children were required across the guideline the GDG decided that a Delphi Consensus method would be most appropriate to develop these recommendations.

Randomised trials, non-randomised trials, and observational studies (including prognostic studies) were included in the evidence reviews as appropriate. Laboratory studies (in vivo or in vitro) were excluded.

Conference abstracts were not automatically excluded from the review. They were initially assessed against the inclusion criteria and then further processed only if no other full publication was available for that review question, in which case the authors of the selected abstracts would have been contacted for further information. Most reviews had full publications available and therefore no conference abstracts which were found through searches were included. Conference abstracts in Cochrane reviews were included when they met the review inclusion criteria and authors were not contacted. Literature reviews, letters and editorials, non-English language publications and unpublished studies were excluded.

The review protocols are presented in Appendix C in the full version of the original guideline document. Excluded studies (with their exclusion reasons) are listed in Appendix J and K in the full version of the original guideline document.

Type of Studies

For most intervention reviews in this guideline, parallel randomised trials (RCTs) were included because they are considered the most robust type of study design that could produce an unbiased estimate of the intervention effects.

For reviews of interventions where no randomised trials of pressure ulcers existed for pressure ulcers it was agreed by the GDG that it would not look at randomised trials of wounds. The GDG felt that wounds were significantly different in etiology from pressure ulcers and therefore thought it more appropriate to review a lower level of data on pressure ulcers. Therefore where there were no randomised trials, cohort studies were

included.

Evidence of Cost-effectiveness

The GDG is required to make decisions based on the best available evidence of both clinical and cost effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits (that is, their 'cost effectiveness') rather than the total implementation cost. Thus, if the evidence suggests that a strategy provides significant health benefits at an acceptable cost per patient treated, it should be recommended even if it would be expensive to implement across the whole population.

Evidence on cost effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist undertook:

- A systematic review of the published economic literature
- New cost-effectiveness analysis in priority areas

Literature Review

The health economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts – full papers were then obtained.
- Reviewed full papers against pre-specified inclusion and exclusion criteria to identify relevant studies.

Inclusion and Exclusion

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost–utility, cost–effectiveness, cost–benefit and cost–consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially includable as economic evidence.

Studies that only reported cost per hospital (not per patient), or only reported average cost effectiveness without disaggregated costs and effects, were excluded. Abstracts, posters, reviews, letters, editorials, comment articles, foreign language publications and unpublished studies were excluded.

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available, then other less relevant studies may not have been included. Where exclusions occurred on this basis, this is noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist in Appendix G of The Guidelines Manual, and the health economics review protocol in Appendix C in the full version of the original guideline document.

See additional details regarding search filters and terms in Appendix F in the full version of the original guideline document.

Number of Source Documents

The number of studies identified for each topic and clinical question is provided in Appendices D and E in the full version of the original guideline document (see the "Availability of Companion Documents" field).

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Level	Description
High	Further research is very unlikely to change confidence in the estimate of effect.

Level	Description
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Evidence of Effectiveness

The evidence was reviewed following the steps shown schematically in Figure 1 in the full version of the original guideline document:

- Relevant studies were critically appraised using the appropriate checklists as specified in The Guidelines Manual. For prognostic studies, quality was assessed using the checklist for Prognostic studies (NICE Guidelines Manual, 2009 [see the "Availability of Companion Documents" field]).
- Key information was extracted on the study's methods and PICO (patient, intervention, comparison and outcome) factors and results were presented in evidence tables (Appendix G in the full version of the original guideline document).
- Summaries of the evidence were generated by outcome (included in the relevant chapter write-ups) and were presented in Guideline Development Group (GDG) meetings:
    - Randomised trials: meta-analysed, where appropriate and reported in Grading of Recommendations Assessment, Development and Evaluation (GRADE) profiles.
    - Prognostic studies (risk tools): data for risk assessment tools were summarised either as the area under the receiver operating characteristics (ROC) curve (AUC) or as coupled sensitivity and specificity pairs for particular thresholds. Meta-analysis was not conducted and the data were summarised across studies as the median with its 95% confidence interval (CI), together with the range of values across studies; for sensitivity and specificity the median sensitivity was reported, with its corresponding specificity. These summaries were reported where possible in the GRADE profile format. Results were reported in tables in the text only for the 3 thresholds per risk assessment tool that maximised both sensitivity and specificity, with a preference for sensitivity.
    - Prognostic studies (risk factors): data for skin assessment methods were presented as the odds ratio or risk ratio, with their 95% CI. Meta-analysis was not conducted and the data were summarised across studies as the median with its 95% CI, together with the range of values across studies. These summaries were reported in the GRADE profile format, where possible.

At least 20% of each of the above stages of the reviewing process was quality assured by the second reviewer to eliminate any potential of reviewer bias or error.

Data Synthesis for Intervention Reviews

Where possible, meta-analyses were conducted to combine the results of studies for each review question using Cochrane Review Manager (RevMan5) software. Where studies reported data which could not be analysed by meta-analysis a narrative summary is provided.

Fixed-effects (Mantel-Haenszel) techniques were used to calculate pooled risk ratios (relative risk) for binary outcomes. Where there were zero events in either arm of a trial the GDG used Peto odds ratios (OR). When 1 of the interventions has zero events, the computation of the meta-analysis risk ratio or its standard error becomes unstable (dividing by zero). The inverse variance methods including random effects models take this into account by adding 0.5 to the appropriate cell (and, to some extent, so do the Mantel Haenszel methods), but this tends to bias the effect estimate and/or the standard error. The best approach is the Peto fixed effects method for odds ratios (provided there is no substantial imbalance

between treatment and control group sizes within studies, and treatment effects are not exceptionally large). The Peto OR method does not make this correction for zero events, but the GDG note that the method only gives an approximation to the odds ratio.

For continuous outcomes, measures of central tendency (mean) and variation (standard deviation [SD]) were required for meta-analysis. Data for continuous outcomes were analysed using an inverse variance method for pooling mean differences, and where the studies had different scales, standardised mean differences were used. A generic inverse variance option in Review Manager was used if any studies reported solely the summary statistics and 95% CI (or standard error [SE]) – this included any hazard ratios reported. However, in cases where standard deviations were not reported per intervention group, the SE for the mean difference was calculated from other reported statistics - p-values or 95% CI; meta-analysis was then undertaken for the mean difference and standard error using the generic inverse variance method in RevMan5 software. Stratified analyses were predefined for some review questions at the protocol stage when the GDG identified that these strata are different in terms of biological and clinical characteristics and the interventions were expected to have a different effect on these groups of people. Statistical heterogeneity was assessed by visually examining the forest plots, and by considering the chi-squared test for significance at $p<0.1$ and the I-squared inconsistency statistic (with an I-squared value of more than 50% indicating considerable heterogeneity). Where considerable heterogeneity was present, the GDG carried out subgroup analyses. Subgroup analyses were carried out, investigating the effect of subgroups pre-specified by the GDG. If the heterogeneity still remained, a random effects (DerSimonian and Laird) model was employed to provide a more conservative estimate of the effect.

For interpretation of the binary outcome results, differences in the absolute event rate were calculated using the GRADEpro software, for the median event rate across the control arms of the individual studies in the meta-analysis. The hazard ratio can be translated into an absolute difference in the proportion of patients who had an event at a particular time point, assuming proportional hazards. This is calculated using GRADEpro software. Absolute risk differences were presented in the GRADE profiles and in a clinical summary of findings tables, for discussion with the GDG.

Data Synthesis for Prognostic Factor Reviews

Prognostic data for risk assessment and skin assessment were analysed in 3 main ways:

Firstly, some studies were randomised trials that compared 2 assessment tools, and gave preventative treatment on the basis of the prognostic assessment. This was the ideal approach for prognostic studies and analysis was conducted as in the previous section.

Secondly, the skin assessment tools were analysed as prognostic factor data. ORs or risk ratios (RRs), with their 95% CI for the effect of the pre-specified prognostic factors were extracted from the papers. Studies of lower risk of bias were preferred, taking into account the analysis and the study design; in particular, prospective cohort studies that reported multivariable analyses for that outcome, which included key confounders as identified by the GDG at the protocol stage, and also took into account preventative treatment in the analysis. Where multivariable analyses were not reported, summary statistics were calculated from 2x2 tables derived from the raw data.

Thirdly, the predictive ability of risk assessment tools was analysed. Data were extracted in 2 ways: as the area under the ROC curve (with its 95% CI), to take account of the multiple thresholds for these tools. Coupled forest plots of sensitivity and specificity with their 95% CI across studies (at various thresholds) were produced for each risk tool, using RevMan5 software. In order to do that, 2x2 tables (the number of true positives, false positives, true negatives and false negatives) were either directly taken from the study if given or derived from raw data, or were calculated from the set of test accuracy statistics.

To allow comparison between tests, summary ROC curves were generated for each prognostic test from the pairs of sensitivity and specificity calculated from the 2x2 tables. This was done only for the studies comparing more than 1 risk tool, and thresholds were selected that maximised both sensitivity and specificity. An ROC plot shows true positive rate (that is sensitivity) as a function of false positive rate (that is 1 – specificity). Data were entered into RevMan5 software and ROC curves were fitted using the Moses Littenburg approach.

AUC data for each study was also plotted on a graph, for each prognostic test: the AUC describes the overall prognostic accuracy across the full range of thresholds. The GDG agreed on the following criteria for AUC: below 0.50 = worse than chance; 0.50-0.60 = very poor; 0.61-0.70 = poor; 0.71-0.80 = moderate; 0.81-0.92 = good; 0.91-1.00 = excellent or perfect test.

Preference was given to studies comparing more than 1 risk tool in the same participants.

Heterogeneity or inconsistency amongst studies was visually inspected in the forest plots. Heterogeneity in the area under the curve was investigated for the Braden scale in terms of preventative treatment, number of pressure ulcers (more than 100, 10-100 and less than 10), population (ICU versus general wards and long term care) and mean age (50-60 years, 60-70 years, 70-80 years).

Data Synthesis for Diagnostic Reviews

Two reviews, measurement of pressure ulcers and categorisation of pressure ulcers, were diagnostic in nature. However the GDG agreed that there is not a gold standard for measurement or categorisation therefore a straight-forward diagnostic test accuracy review was not possible. A systematic review was found for measurement of pressure ulcers which was relevant for this question and was comprehensive enough to answer the review question. This systematic review used a modified version of the Quality Assessment for Diagnostic Studies (QUADAS) tool, which was appropriate for this review. As the categorisation review was similar in nature to the measurement question it was thought appropriate to use the modified QUADAS tool for consistency of reviews.

Data Synthesis for Qualitative Reviews

Two reviews, training and education of healthcare professionals and information required for patients (in regards to pressure ulcers), were qualitative in nature. This entailed searching and obtaining studies according to the protocol and extracting the details from each study. Themes were obtained from the studies and reported in the review with further details underpinning the themes.

Type of Analysis

Estimates of effect from individual studies were based on the author reported data. As a preference available case analysis (ACA) was used and if this was not reported intention-to-treat analysis (ITT) with imputation was then used.

The ACA method is preferred to an ITT with imputation analysis, in order to avoid making assumptions about the participants for whom outcome data were not available, and furthermore assuming that those with missing outcome data have the same event rate as those who continue. In addition, ITT analysis tends to bias the results towards no difference, and therefore the effect may be smaller than in reality.

Appraising the Quality of Evidence by Outcome

The evidence for outcomes from the included RCTs and observational studies (when appropriate) was evaluated and presented using the 'GRADE toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/). The software (GRADEprofiler) developed by the GRADE working group was used to assess the evidence quality for each outcome, taking into account individual study quality factors and the meta-analysis results. Results were presented in GRADE profiles ('GRADE tables'), which consist of two adjacent sections: the 'Clinical/Economic Study Characteristics' table includes details of the quality assessment while the 'Clinical/Economic Summary of Findings' table includes pooled outcome data and an absolute measure of the intervention effect and the summary of quality of evidence for that outcome. In this table, the columns for intervention and control indicate summary measures and measures of dispersion (such as mean and standard deviation or median and range) for continuous outcomes and frequency of events (n/N: the sum across studies of the number of participants with events divided by sum of the number of completers) for binary outcomes.

The evidence for each outcome was examined separately for the quality elements listed and each graded using the quality levels listed below. The main criteria considered in the rating of these elements are discussed below. Footnotes were used to describe reasons for grading a quality element as having serious or very serious problems. The ratings for each component were summed to obtain an overall assessment for each outcome.

1. A quality rating was assigned, based on the study design and the type of review. For intervention reviews, randomised controlled trials (RCTs) start HIGH and observational studies as LOW.
2. The rating was then downgraded for the specified criteria: risk of bias (study limitations), inconsistency, indirectness, imprecision and publication bias. These criteria are detailed in the full version of the guideline. Evidence from observational studies (that had not previously been downgraded) was upgraded if there was: a large magnitude of effect, dose-response gradient, and if all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results showed no effect. Each quality element considered to have "serious" or "very serious" risk of bias was rated at -1 or -2 points respectively.
3. The downgraded/upgraded marks were then summed and the overall quality rating was revised. For example, all RCTs started as HIGH and the overall quality became MODERATE, LOW or VERY LOW if 1, 2 or 3 points were deducted respectively.
4. The reasons used for downgrading were specified in the footnotes.

The details of criteria used for each of the main quality elements are discussed further in Sections 3.3.1.7 to 3.3.1.12 on the full version of the original guideline document.

Evidence of Cost-effectiveness

The GDG is required to make decisions based on the best available evidence of both clinical and cost effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits (that is, their 'cost effectiveness') rather than the total implementation cost. Thus, if the evidence suggests that a strategy provides significant health benefits at an acceptable cost per patient treated, it should be recommended even if it would be expensive to implement across the whole population.

Evidence on cost effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist undertook:

- A systematic review of the published economic literature
- New cost-effectiveness analysis in priority areas

Literature Review

The health economist:

- Critically appraised relevant studies using the economic evaluations checklist as specified in The Guidelines Manual.
- Extracted key information about the studies' methods and results into evidence tables (included in Appendix H; see the "Availability of Companion Documents" field)
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter for each review question).

NICE Economic Evidence Profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows an assessment of applicability and methodological quality for each economic evaluation, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from The guidelines manual. It also shows incremental costs, incremental effects (for example, quality-adjusted life years [QALYs]) and the incremental cost-effectiveness ratio, as well as information about the assessment of uncertainty in the analysis. See Table 2 in the full version of the original guideline document for more details.

If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

This guidance was developed in accordance with the methods outlined in the NICE Guidelines Manual 2009 (see the "Availability of Companion Documents" field).

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline. The group met every 4-6 weeks during the development of the guideline.

Developing Recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendix G and H of the full version of the original guideline document.
- Summary of clinical (GRADE tables) and economic evidence and quality (as presented in individual chapters in the full version of the original guideline document).
- Forest plots and receiver operating characteristics (ROC) curves (see Appendix I in the full version of the original guideline document).
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (see Appendix L in the full version of the original guideline document).

Recommendations were drafted on the basis of the GDG's interpretation of the available evidence, taking into account the trade off between benefits, harms and costs of different courses of action. This was either done formally in an economic model, or informally. Firstly, the net benefit

over harm was considered (clinical effectiveness), using the critical outcomes. When this was done informally, the GDG took into account the clinical benefits/harms when 1 intervention was compared with another. The assessment of net benefit was moderated by the importance placed on the outcomes (the GDG's values and preferences), and the confidence the GDG had in the evidence (evidence quality). Secondly, it was assessed whether the net benefit justified the costs.

When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on their expert opinion. The considerations for making consensus based recommendations included the balance between potential harms and benefits, economic or other implications compared to the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were done through discussions in the GDG. The GDG could also consider whether the uncertainty is sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation. The wording of recommendations was agreed by the GDG and focused on the following factors:

- On the actions health professionals need to take
- Include what readers need to know.
- Reflect the strength of the recommendation (for example the word "offer" was used for strong recommendations and "consider" for weak recommendations).
- Emphasise the involvement of the patient (and/or their carers if needed) in decisions on treatment and care.
- Follow NICE's standard advice on recommendations about drugs, waiting times and ineffective interventions.

The main considerations specific to each recommendation are outlined in the 'Recommendations and link to evidence' sections within each chapter.

Delphi Consensus Methods

It is recognised that in the area of pressure ulcer prevention and management there is often limited high quality evidence available. This is further exaggerated in the prevention and management of pressure ulcers in children (including neonates, infants, children and adolescents).

During development of the guideline, due to the scarcity of evidence identified, it was agreed by the GDG that this would be an area in which the use of formal consensus methods would be appropriate. A modified Delphi approach was chosen as this would provide a robust approach to allow the GDG to develop recommendations. Where there are any randomised trials or high quality cohort studies available these will be included in a review. It is acknowledged that during development of the guideline, there are other areas or population subgroups where evidence of the required quality is not identified. In these cases lower levels of evidence was searched for, for example cohort studies, for the GDG to base their recommendations on. If no evidence was found, GDG consensus was used to form recommendations, in line with NICE methodology.

The methods for agreeing and developing the Delphi consensus statement are outlined in Chapter 4 of the full version of the original guideline document, and a full report can be found in Appendix N the full version of the original guideline document.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally 'must' (or 'must not') is used if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer…') are used when the GDG is confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other

options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Cost Analysis

Undertaking New Health Economic Analysis

As well as reviewing the published economic literature for each review question, as described above, new economic analysis was undertaken by the health economist in selected areas. Priority areas for new health economic analysis were agreed by the Guideline Development Group (GDG) after formation of the review questions and consideration of the available health economic evidence.

The GDG identified negative pressure wound therapy and repositioning as the highest priority areas for original economic modelling, as there was limited existing evidence and wide variation in current practice in both of these areas.

The following general principles were adhered to in developing the cost-effectiveness analysis:

- Methods were consistent with the National Institute for Health and Care Excellence (NICE) reference case.
- The GDG was involved in the design of the models, selection of inputs and interpretation of the results.
- Model inputs were based on the systematic review of the clinical literature supplemented with other published data sources where possible.
- When published data was not available GDG expert opinion was used to populate the models.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The models were peer-reviewed by another health economist at the National Clinical Guideline Centre (NCGC).

Full methods for the cost-effectiveness analysis for negative pressure wound therapy and repositioning are described in Appendix L of the full version of the original guideline document.

Cost-effectiveness Criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money. In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

a. The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
b. The intervention cost less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend 1 that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'Recommendations and link to evidence' section of the relevant chapter, with reference to issues regarding the plausibility of the estimate or to the factors set out in 'Social value judgements: principles for the development of NICE guidance'. When QALYs or life years gained are not used in the analysis, results are difficult to interpret unless 1 strategy dominates the others with respect to every relevant health outcome and cost.

See the individual chapters in the full version of the original guideline document (see the "Availability of Companion Documents" field) for discussions of the cost-effectiveness of specific recommendations.

In the Absence of Economic Evidence

When no relevant published studies were found, and a new analysis was not prioritised, the GDG made a qualitative judgement about cost-effectiveness by considering expected differences in resource use between options and relevant UK NHS unit costs alongside the results of the clinical review of effectiveness evidence.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The guidance is subject to a 6 week public consultation and feedback as part of the quality assurance and peer review the document. All comments received from registered stakeholders are responded to in turn and posted on the NICE website when the pre-publication check of the full guideline occurs.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate prevention and management of pressure ulcers

See the "Trade off between clinical benefits and harms" sections in the full version of the original guideline document (see the "Availability of Companion Documents" field) for additional details about benefits of specific interventions.

Potential Harms

- Some strategies for offloading heel pressure (for example, using cushions) can result in an increase in pressure on other sites.
- Some methods used for measuring volume may be harmful to the person who has a pressure ulcer and can cause pain and discomfort, particularly in neonates, infants, children and young people.
- The Guideline Development Group (GDG) did not consider there would be any direct harms from the use of the reviewed tools. Inaccurate or unreliable tools could be regarded as an indirect source of potential harm for the individual with the pressure ulcer.
- Any consideration of using a dynamic support surface should account for the individual patient factors and to minimise any potential harms, the size and weight of the child or young person should be carefully considered and an appropriate dynamic support surface selected.
- System or topical antibiotics may cause skin irritation, rash, itching, allergic reaction, normal flora disruption, toxicity, and treatment-related pain.

See the "Trade off between clinical benefits and harms" sections in the full version of the original guideline document (see the "Availability of Companion Documents" field) for additional details about potential harms of specific interventions.

Qualifying Statements

Qualifying Statements

- This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

- Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the Department of Health's advice on consent . If someone does not have capacity to make decisions, healthcare professionals should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards .
- NICE has produced guidance on the components of good patient experience in adult National Health Service (NHS) services. All healthcare professionals should follow the recommendations in Patient experience in adult NHS services .
- If a young person is moving between paediatric and adult services, care should be planned and managed according to the best practice guidance described in the Department of Health's Transition: getting it right for young people .
- Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people at risk of developing or who have developed pressure ulcers. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.
- The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.
- For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision.

Implementation of the Guideline

Description of Implementation Strategy

The National Institute for Health and Care Excellence (NICE) has developed tools and resources to help organisations implement this guidance. These are available on the NICE Web site (see also the "Availability of Companion Documents" field).

Key Priorities for Implementation

The following recommendations have been identified as priorities for implementation.

Adults: Risk Assessment

Carry out and document an assessment of pressure ulcer risk for adults:

- Being admitted to secondary care or care homes in which National Health Service (NHS) care is provided or
- Receiving NHS care in other settings (such as primary and community care and emergency departments) if they have a risk factor, for example:
  - Significantly limited mobility (for example, people with a spinal cord injury)
  - Significant loss of sensation
  - A previous or current pressure ulcer
  - Nutritional deficiency
  - The inability to reposition themselves
  - Significant cognitive impairment

Adults: Skin Assessment

Offer adults who have been assessed as being at high risk of developing a pressure ulcer a skin assessment by a trained healthcare professional. The assessment should take into account any pain or discomfort reported by the patient and the skin should be checked for:

- Skin integrity in areas of pressure
- Colour changes or discoloration*
- Variations in heat, firmness and moisture (for example, because of incontinence, oedema, dry or inflamed skin)

*Healthcare professionals should be aware that non-blanchable erythema may present as colour changes or discolouration, particularly in darker skin tones or types.

All Ages: Care Planning

Develop and document an individualised care plan for neonates, infants, children, young people and adults who have been assessed as being at high risk of developing a pressure ulcer, taking into account:

- The outcome of risk and skin assessment
- The need for additional pressure relief at specific at-risk sites
- Their mobility and ability to reposition themselves
- Other comorbidities
- Patient preference

Adults: Repositioning

Encourage adults who have been assessed as being at risk of developing a pressure ulcer to change their position frequently and at least every 6 hours. If they are unable to reposition themselves, offer help to do so, using appropriate equipment if needed. Document the frequency of repositioning required.

Adults: Devices for Prevention of Pressure Ulcers

Use a high-specification foam mattress for adults who are:

- Admitted to secondary care
- Assessed as being at high risk of developing a pressure ulcer in primary and community care settings

Neonates, Infants, Children and Young People: Risk Assessment

Carry out and document an assessment of pressure ulcer risk for neonates, infants, children and young people:

- Being admitted to secondary care or tertiary care
- Receiving NHS care in other settings (such as primary and community care and emergency departments) if they have a risk factor, for example:
    - Significantly limited mobility (for example, people with a spinal cord injury)
    - Significant loss of sensation
    - A previous or current pressure ulcer
    - Nutritional deficiency
    - The inability to reposition themselves
    - Significant cognitive impairment

All Ages: Healthcare Professional Training and Education

Provide training to healthcare professionals on preventing a pressure ulcer, including:

- Who is most likely to be at risk of developing a pressure ulcer
- How to identify pressure damage
- What steps to take to prevent new or further pressure damage
- Who to contact for further information and for further action

Provide further training to healthcare professionals who have contact with anyone who has been assessed as being at high risk of developing a pressure ulcer. Training should include:

- How to carry out a risk and skin assessment
- How to reposition
- Information on pressure redistributing devices
- Discussion of pressure ulcer prevention with patients and their carers
- Details of sources of advice and support

Adults: Management of Heel Pressure Ulcers

Discuss with adults with a heel pressure ulcer and if appropriate, their carers, a strategy to offload heel pressure as part of their individualised care plan.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Clinical Guideline Centre. Pressure ulcers: prevention and management of pressure ulcers. London (UK): National Institute for Health and Care Excellence; 2014 Apr. 37 p. (Clinical guideline; no. 179).

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

National Guideline Centre - National Government Agency [Non-U.S.]

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Guideline Committee

Guideline Development Group (GDG)

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

At the start of the guideline development process all Guideline Development Group (GDG) members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest, which were also recorded (Appendix B in the full version of the original guideline document; see the "Availability of Companion Documents" field).

Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate. The details of declared interests and the actions taken are also shown in Appendix B in the full version of the original guideline document.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Nursing, National Institute for Health and Clinical Excellence (NICE). The management of pressure ulcers in primary and secondary care. A clinical practice guideline. London (UK): Royal College of Nursing; 2005 Sep 22. 245 p. [485 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

Availability of Companion Documents

The following are available:

- Pressure ulcer management: the prevention and management of pressure ulcers in primary and secondary care. Full guideline. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. 710 p. (Clinical guideline; no 179). Electronic copies: Available in from the National Institute for Health and Care Excellence (NICE) Web site .

- Pressure ulcer prevention: the prevention and management of pressure ulcers in primary and secondary care. Full guideline. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. 416 p. (Clinical guideline; no 179). Electronic copies: Available from the NICE Web site .
- Pressure ulcers: prevention and management of pressure ulcers. Appendices. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. (Clinical guideline; no 179). Electronic copies: Available from the NICE Web site .
- Pressure ulcers: prevention and management of pressure ulcers. Baseline assessment tool. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. (Clinical guideline; no 179). Electronic copies: Available from the NICE Web site .
- Pressure ulcers. Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. 9 p. (Clinical guideline; no 179). Electronic copies: Available from the NICE Web site .
- The guidelines manual 2009. London (UK): National Institute for Health and Care Excellence (NICE); 2009 Jan. Electronic copies: Available from the NICE Archive Web site .

Patient Resources

The following is available:

Pressure ulcer prevention, treatment and care. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Apr. Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI Institute on August 5, 2014.

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